Galenisys 11 rue Notre Dame de Nazareth , 75003 Paris, France. Tel : +33145554414 or +33632329927

February 2023 | NUMBER 23

NEWSLETTR

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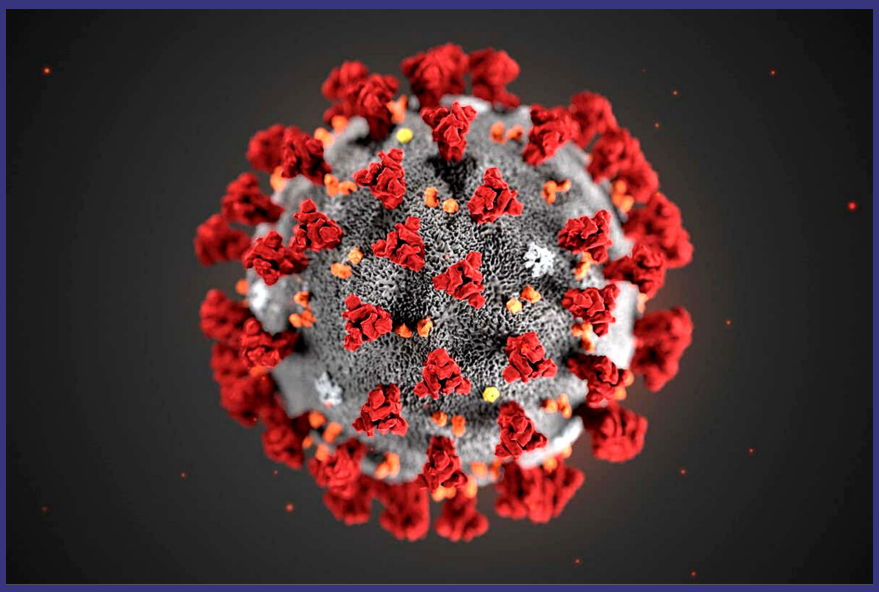
Tony Dunford Editor

PHARMA BOSSES & CEPI AT DAVOS

By The Editor

In January the World Economic Forum (WEF) resumed in Davos Switzerland. This year it included important figures from the Pharmaceutical Industry who took the opportunity of talking to the media. Of particular interest were the sessions organised by the Health and Healthcare Division of the WEF, to discuss the measures needed to deliver future epidemic countermeasures even more quickly than those achieved during the COVID epidemic.

Davos was the "birthplace" of CEPI and its CEO, Dr Richard Hatchett chaired a panel consisting of Helen E. Clark (Fmr PM of New Zealand), Tony Blair (former UK P M and now Executive Chairman of The Institute for Global Change), Albert Bourla (CEO of Pfizer), Silvino Augusto Jose Moreno (Minister of Industry and Trade, Mozambique) and Shyam Bishen (Head, Shaping the Future of Health and Healthcare, & Exec Committee, WEF).



Here is a summary of the contributors answers to the question....

HOW CAN WE DELIVER EPIDEMIC COUNTERMEASURES MORE QUICKLY?

Firstly, remember the economic damage & loss of life the epidemic caused. Then imagine the global destabilisation which would occur if we had the equivalent of two of these in a decade - unfortunately global trends make this more likely. (Helen Clark)
Secondly, accelerate vaccine development. The lead time of 323 days from release of the DNA sequencing of the new virus to first Emergency Authorization during Covid, was achieved by the unprecedented efforts & cooperation, hugely encouraging. CEPI's project is to now reduce that time to 100 days!)
Thirdly increase manufacturing capacity interalia via a decentralised manufacturing strategy. An example is the CEPI planned support for a project with Institute Pasteur Dakar which Dr Hatchett announced.
Fourthly address the political issues:
Speakers highlighted the "vaccine nationalism" experienced, (both US & India banned exports for a while) However, whereas national leaders will always be under pressure to protect "their own" first;Albert Bourla noted no nation has vaccine sovereignty, all needed to import some of the 100s of materials or components from dozens of other countries. In future "Nobody (country) should stop anything (medical) crossing borders".

When asked what would facilitate Approval & vaccine distribution in Africa, Minister Morena hoped that a future African Medicines Agency would be aided by effective Free Trade Area(s) in the continent.

Tony Blair stressed "it's vital to maintain the political focus" (of national leaders); by stressing the plans proposed, will likely be needed by them in the next few years not in the vague future.
And he highlighted the need to identify mechanisms which will bring the right diverse actors together to cooperate in key areas, plus the need for in country digital infrastructure to collect & rapidly share data on disease type, spread, vaccination, & treatments.
He distinguished between "forgiveable & unforgiveable politics" with the undermining of established medical facts an example of the latter.

Steve Biddulph +33 6 32 32 99 27 Steve.biddulph@galenisys-pc.com

Albert Bourla was asked to explain the "success factors" which were key in "the heroic medical and scientific response to the epidemic" (Dr Hatchett). He answered:

- The extraordinary hard work & cooperation between researchers in Pfizer, Moderna & Astra Zeneca, and the FDA & EMA regulators.
- A presence of a thriving Life Sciences Industry.
- And at Pfizer, the company taking a "series of 50/50 decisions" including backing unproven mRNA technology and being willing to scale up their (total) vaccine capacity from 200mio doses pa to 3bio in the 1st year of the pandemic.

Looking back, Bourla mentioned the biggest challenges were political - the ability to use the vaccines – scared Governments closing borders, and some questioning mask usage, the new technology, vaccine efficacy, the "dangers" & and even the existence of Covid.

(A good example of the politization of Covid, was Bourla being confronted with hostile and even misleading questions at Davos such as "… is it time … to give refunds to countries …. (for) an ineffective vaccine" – hence boosting science denial & some "journalists" egos – Editor)

CEO of Pfizer Albert Bourla, spoke to Bloomberg & CNBC about what the company had been doing, and was planning. Here are some takeaways:

- Pfizer screen all reported variants for ones that escape from vaccine protection.
- The company believe it will be difficult to eradicate the virus (although most variants disappear)
- Whereas the immunity afforded by current vaccines declines after 3 months (hence "boosters"), Pfizer are working on an annual jab since people are accustomed to this.
- This development product could emerge by mid-2023.
- The company has also started experimenting on a combined flu & covid vaccine.
- Regarding the 1 billion doses of COVID vaccine that the US government had bought at cost from Pfizer and offered free to the world; he remarked ruefully that these "had not been absorbed" by the developing world. (ie the problem was the weakness in the infrastructure, and shortage of healthcare professionals in these countries, not "Vaccine Apartheid")
- Although Pfizer had shipped some mNRA vaccines to China, none had been requested by the Chinese Government.
- He confirmed Pfizer will make 23 of its medicines—many of them patented—available to 45 low-income countries at a not-for-profit price.
- This brings the total number of products on offer to such countries on this basis to around 500

Ambitious Pfizer:

- In the next 18 months Pfizer plan to launch no less than 19 new products, including vaccines & anti-cancer drugs.

Also in Davos was Stephane Mancel the CEO of Moderna. He was on the panel at the "State of the Pandemic" session. He confirmed to Bloomberg that Moderna are building vaccine factories in Canada & Australia, have plans to do so in Britain & Kenya, and hoped that other suitable locations would be found internationally, so that Moderna could rapidly expand future production from established facilities. He too spoke of further efforts to reduce the timescale.

The general impression is that both companies are working hard to further compress the "discovery to launch" leadtimes by planning activities in parallel, & also/consequentially, being willing to invest before (100%) proof.

DON'T GET ILL NOW

By Terry Simmons
Galenisys Technical Director. Extensive experience across many roles in Aseptic Manufacturing, the Supply Chain, & Project Management.

If you are reading this in one of the richer countries of the world you've probably seen media interviews recently in which doctors and / or nurses are complaining of fatigue & burnout; and patients are bemoaning waiting times.

Whereas during the height of the epidemic there were virtually no examples of the intensive care capacity in hospitals being exceeded; currently healthcare systems throughout the developed world are under sustained & unprecedented pressure.

Pre-epidemic, below 9% of GDP was spent on healthcare by the OECD countries. This is now almost 10% Looking at it another way - more is spent per person in these nations than ever before.

Where's the money been going? Obviously, there was the cost of testing, tracing, and vaccinations. But now there's a bigger salary bill. In 2021 the overall number of people working in hospitals in 6 OECD countries was 9% higher than pre-pandemic.

Has healthcare productivity declined then? Perhaps, and for understandable reasons. Firstly Covid & non-Covid patients need to be (screened) & segregated. Secondly additional "gowning-up" (donning items of personal protective clothing) takes time; as does increased anti-Covid cleaning & sanitation. Thirdly Covid infections depleted the numbers of healthcare employees at work.

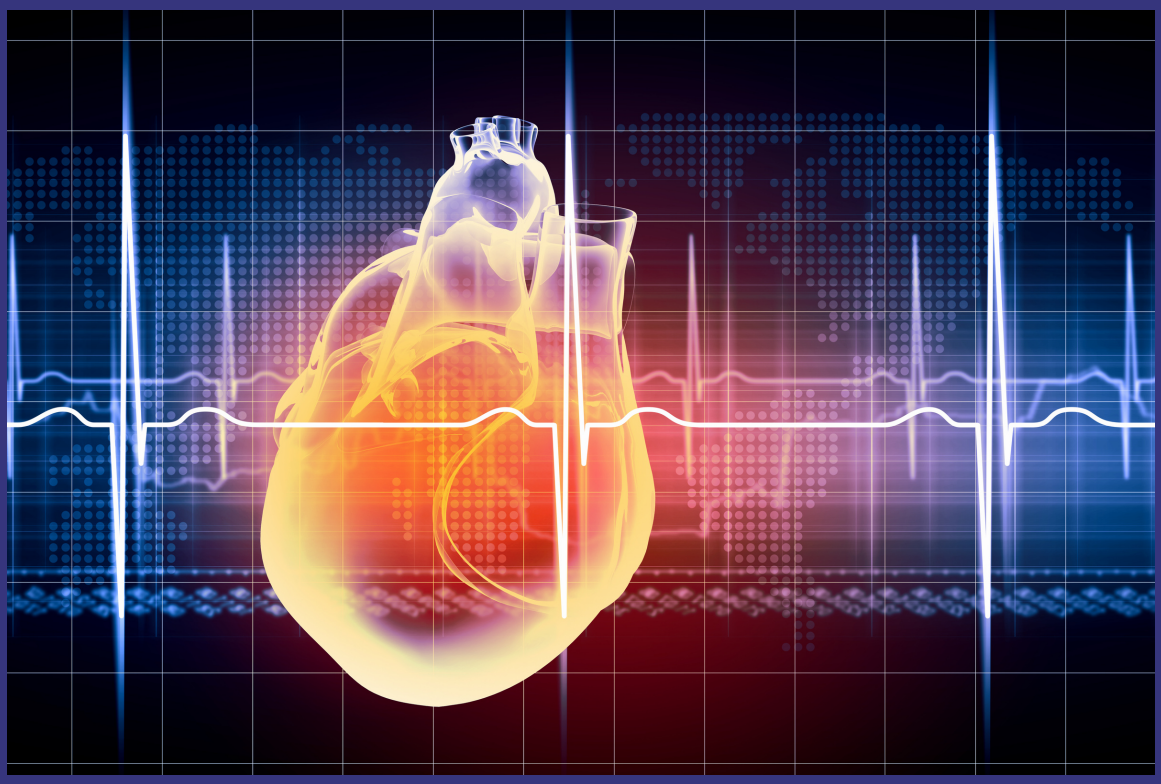
The current backlog of routine operations, and illness arising from cancelled screening & diagnosis, is a dispiriting outlook for these tired workers.

Ahead is the continuing increase in elderly populations, the likelihood that Covid is here to stay, and the backlogs; which means that the limited additional amounts which (indebted) governments are able to put into healthcare may not be sufficient to return healthcare systems to the relative efficiency of the pre-epidemic years.

Logically, what could / should the response be?

Hopefully there will be an increased emphasis on Prevention & Self Help.
More is now known than ever before about the causes of some diseases and how to avoid them. Three commonly occurring factors are diet, exercise, and addiction. Sustained public awareness campaigns on these issues to stress the importance of the healthy lifestyle ought to be highly cost effective, (eg as with the reduction in cigarette smoking).

In our October edition, we talked about “DIGITALLY MEDIATED HEALTHCARE”, and wearable devices, which can – continuously – monitor performance or levels, and detect symptoms, if they occur. An encouraging example of this, that I heard of recently, was a friend who had a fitted pacemaker & defibrillator. Whilst asleep, the latter activated his pacemaker & signalled anomalies to a remote monitoring service. The following day the service recommended consulting his specialist.



Given the situation in national healthcare services on can expect to see an increase in the use of **these Home Diagnostics, & Health Wearables; and a further rise in Consumer Health products, & Private Clinics.**

In November, Amazon launched “Amazon Clinic”, an online service offering virtual healthcare for 20 conditions, in most US states. This follows its’ $3.9bio takeover of One Medical; and shows which way the wind is blowing.

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WHY DOES IT TAKE SO LONG?

The Editor

In Galenisys November edition we featured the scandal of the contaminated cough syrups. The immediate action demanded by WHO of suppliers, manufacturers, regulators and governments reads like lack of compliance with whole chapters of the first GMP Guides of 50+ years ago!!

Over the past four months, countries have reported on several incidents of over-the-counter cough syrups for children with confirmed or suspected contamination from diethylene glycol* (DEG) and ethylene glycol* (EG). The cases are from at least seven countries, associated now with more than 300 fatalities in three of these countries. Most are young children under the age of five. (*toxic chemicals used as industrial solvents and antifreeze agents that can be fatal even taken in small amounts).

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Here's what WHO called on regulators and governments to do in 2 further alerts last month:

- detect and remove from circulation in their respective markets any substandard medical products that have been identified in the WHO medical alerts referred to above as potential causes of deaths and disease;
- ensure that all medical products in their respective markets are approved for sale by competent authorities and obtainable from authorized/licensed suppliers;
- assign appropriate resources to improve and increase risk-based inspections of manufacturing sites within their jurisdiction in accordance with international norms and standards;
- increase market surveillance including risk-based targeted testing for medical products released in their respective markets including informal markets; and
- enact and enforce, where relevant and as appropriate, laws and other relevant legal measures to help combat the manufacture, distribution and/or use of substandard and falsified medicines.

WHO calls on manufacturers of medicines to:

- only purchase pharmaceutical grade excipients from qualified and bona fide suppliers;
- conduct comprehensive testing upon receipt of supplies and before use in manufacture of finished products;
- provide assurance of product quality including through certificates of analyses based on appropriate testing results; and
- keep accurate, complete and proper records of purchase of materials, testing, manufacture, and distribution to facilitate traceability during investigations in case of incidents.

WHO urges all suppliers and distributors of medical products to:

- always check for signs of falsification and physical condition of medicines and other health products they distribute and/or sell;
- only distribute and/or sell medicines authorized by, and from sources approved by competent authorities;
- keep accurate, complete and proper records relating to the medicines and their distribution and/or sale; and
- engage competent personnel to handle medicines and provide advice to the public on appropriate use of the medicines.

Many news outlets carried this story. As well as the countries above, the WHO told Reuters on Monday that the Philippines, Timor Leste, Senegal and Cambodia may be affected because they may have the medicines on sale.

The earlier alerts asked for the medicines to be removed from the shelves, for cough syrups made by India's Maiden Pharmaceuticals and Marion Biotech, which are linked with deaths in the Gambia and Uzbekistan respectively.

It also issued a warning last year for cough syrups made by four Indonesian manufacturers, PT Yarindo Farmatama, PT Universal Pharmaceutical, PT Konimex and PT AFI Pharma, that were sold domestically.

APPLY THE RIGHT WAY

By Jose Zapata
Galenisys Pharma Senior Expert. Pharmacist with frontline experience in Quality, Operations & Project Management.
PDD Certified

I would like to remind our readers that the European Medicines Agency has made it obligatory from the 31st of January this year to use the new system for all clinical trials applications in the European Union territories:

On 31 January 2023, the use of the Clinical Trials Information System (CTIS) will become mandatory for new clinical trial applications and will serve as the single-entry point for submission by sponsors and for regulatory assessment. This follows one year of transition, during which sponsors could choose whether to submit a new clinical trial application in line with the Clinical Trials Directive or under the new Clinical Trials Regulation (CTR), which entered into application on 31 January 2022.
(There are system releases planned for the first quarter of 2023 and further enhancements will be made throughout 2023)

Eisai & Biogen announced** that a “Lecanemab” slowed the progress of Alzheimer’s disease by a quarter in patients suffering early stages of the illness; in their clinical trial. There’s a long way to go; however, the results give strong support to the amyloid hypothesis that Alzheimer’s is caused by beta-amyloid and another protein, in the brain. Lecanemab uses an attaching antibody to attract immune cells which were seen clearing the protein. The findings show a potentially important way forward.

** New England Journal of Medicine